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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,357	11/17/2003	Hans Nilsson	06275-081003	7635

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EXAMINER	
GEORGE, KONATA M	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 09/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/716,357	NILSSON ET AL.	
	Examiner	Art Unit	
	Konata M. George	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 27-94 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 27-94 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 27-94 are pending in this application.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on November 17, 2003 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 28-32, 36-47, 57-69 and 72-83 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 28, 36, 40, 44, 57, 66, 72 and 78 are broader than the enabling disclosure. The specification discloses the conditions to be treated are seasonal allergic rhinitis, perennial allergic or non-allergic rhinitis, nasal polyps and chronic or recurrent sinusitis however; the claims 28, 36, 40, 44, 57, 66, 72 and 78 are drawn to treating or preventing a condition in the upper respiratory tract. It is the position of the examiner that this could be any condition in the

upper respiratory tract (i.e. asthma, pneumonia, etc.), which is clearly broader than what is in the specification.

3. Claims 40-43, 57-65 and 78-80 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph have been described in *In Re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) breadth of the claims; (6) the amount of direction of guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the claims:
The claims are directed towards a method or treating or preventing a condition of an upper respiratory tract, comprising administering into the nostril of the mammal in need thereof a metered unit dose of an active agent which consist of about 32 μg of budesonide formulated as finely divided particles, suspended in an aqueous medium.

(2) The state of the prior art:
The state of the prior art is low. There are several patents that discuss the use of budesonide WO 97/01337, 5,509,404 and 3,992,534. Each of these patents teaches the use of budesonide in treating certain respiratory conditions.

(3) The relative skill of those in the art:
The relative skill in the art is high. As discussed above it is widely known to use budesonide to treat certain respiratory tract conditions.

(4) The predictability or unpredictability of the art:
The art pertaining to preventing upper respiratory tract conditions is very high. There are many factors that cause upper respiratory tract conditions (i.e. genetics, environmental conditions, etc.). It would be very difficult to prevent a condition of the upper respiratory tract caused by genetics.

(5) The breadth of the claims:
The claims are broad. The claims are directed to treating or preventing a condition of the upper respiratory tract.

(6) The amount of guidance presented:
The specification does not teach how to "use" for the scope of "treating or preventing a condition of the upper respiratory tract" as this would include the flu, common cold, etc. which there is nothing in the specification to teach how to use the budesonide for such methods.

(7) The presence or absence of working examples:
The specification does not provide working examples for the use of the composition used to treat any condition of the upper respiratory tract.

(8) The quantity of experimentation necessary:
The specification did not enable any person skilled in the art to which it pertains to use the invention commensurate with the scope of the claim. In particular the specification failed to enable the skilled artisan to practice the invention without undue experimentation.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 27-94 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,291,445 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application is drawn to the same unit dose as defined in the claims of ('445). The difference between the patent and the copending application is the percentage of particles that have a sphere diameter of 20 μm and the pH. It would have been obvious to one of ordinary skill in that art to produce a unit dose that comprises particles that have the same sphere diameter so that one could deliver a uniform dosage amount in each unit dosage. It is also obvious to one of ordinary skill on the art to use an aqueous medium having a pH that will not affect the pharmacokinetics of the drug.

5. Claims 27-94 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,686,346 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application is drawn to the same unit dose as defined in the claims of ('346). The difference between the patent and the copending application is the percentage of particles that have a sphere diameter of 20 μm and the pH. It would have been obvious to one of ordinary skill in that art to produce a unit dose

that comprises particles that have the same sphere diameter so that one could deliver a uniform dosage amount in each unit dosage. It is also obvious to one of ordinary skill on the art to use an aqueous medium having a pH that will not affect the pharmacokinetics of the drug.

Conclusion

6. Claims 27-94 are rejected.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (571) 272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Konata M. George
Patent Examiner
Art Unit 1616